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UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Milton Hodosh

Serial No. : 09/072,504

Filed : May 4, 1998

For : **METHOD AND COMPOSITION FOR
PREVENTING TOOTH
HYPERSENSITIVITY WHEN USING
PASSIVE BLEACHING AGENTS**

Art Unit : 1614

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**REQUEST FOR INTERFERENCE
WITH PATENT UNDER 37 C.F.R. §1.607**

Assistant Commissioner for Patents
Washington, D.C. 20231

May 3, 2001

Sir:

Applicant respectfully requests that an interference be declared between the above-identified patent application (hereinafter referred to as "the May 1998 Hodosh application") and U.S. Patent No. 5,851,512, issued December 22, 1998, (hereinafter referred to as "the Fischer I patent"), attached hereto as Exhibit 1; U.S. Patent No. 5,855,870, issued January 5, 1999, (hereinafter referred to as "the Fischer II patent"), attached hereto as Exhibit 2; U.S. Patent No. 5,985,249, issued November 16, 1999, (hereinafter referred to as "the Fischer III patent"), attached hereto as Exhibit 3 and U.S. Patent No. 6,036,942, issued March 14, 2000, (hereinafter referred to as "the Fischer IV patent"), attached hereto as Exhibit 4.

I hereby certify that this correspondence is being transmitted by facsimile to the "Assistant Commissioner for Patents Washington, D.C. 20231" on May 3, 2001
STEINBERG & RASKIN, P.C.

BY:

COUNT

Pursuant to 37 C.F.R. §1.607(a)(1), the following Count is proposed.

1. An orally compatible composition comprising:
 - a desensitizing agent for reducing dental pain sensations,
 - a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof, the dental composition having a stickiness so that the dental composition is capable of adhering and retaining a dental tray over a person's teeth for at least about one hour, wherein the dental tray is designed not to exert a mechanical pressure onto the person's teeth and gums, and
 - a bleaching compound.

The proposed count corresponds directly to claim 26 which has been added to the present application via an amendment filed concurrently with this request.

Claim 26 is Supported by the May 1998 Hodosh Application

The proposed count, which is identical to claim 26 of the 1998 Hodosh application, is disclosed in the May 1998 application. Each element of the proposed count is supported by the disclosure of the May 1998 application as follows:

Elements of Claim 26 of the May 1998 Hodosh Application	Where Those Elements Are Disclosed in the May 1998 Hodosh Application
A sticky dental composition adapted for use with a dental tray for treating sensitive teeth:	p. 3, l. 24 - p. 5, l. 3; p. 8, ll. 6-11.
a desensitizing agent for reducing dental pain sensations,	p. 5, ll. 24-26

<p>and a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof, the dental composition having a stickiness so that the dental composition is capable of adhering and retaining a dental tray over a person's teeth for at least about one hour, wherein the dental tray is designed not to exert a mechanical pressure onto the person's teeth and gums; and</p>	<p>p. 6, ll. 13-14; p. 6 l. 23 - p. 7 l. 2.</p>
<p>a bleaching compound.</p>	<p>p. 5, ll. 21-23.</p>

With regard to the limitation that “the dental composition having a stickiness so that the dental composition is capable of adhering and retaining a dental tray over a person's teeth for at least about one hour, wherein the dental tray is designed not to exert a mechanical pressure onto the person's teeth and gums” it is noted that in the specification of the Fischer I patent a suitable sticky matrix material is identified as carboxypolymethylene. It is further noted in the Fischer I patent that suitable carboxypolymethylene may be obtained from B.F. Goodrich Company under the tradename “Carbopol”. (See Fischer I patent, col. 6, ll. 29-39) Finally the Fischer I patent states that the composition of the invention disclosed in the Fischer I patent preferably has a concentration of Carbopol in a range from about 2% to about 12% by weight. (See Fischer I patent, col. 6, l. 60)

In the May 1998 Hodosh application it is recited that the dental composition may contain carboxypolymethylene in an amount up to about 12%. (See p. 6, ll. 26-27). Accordingly the “tackifying agent” of the type recited in claim 1 of the Fischer I patent and in proposed count is clearly supported by the specification of the May 1998 Hodosh application.

In view of the above it is submitted that new claim 26, and thus the proposed count, is clearly supported by the specification of the May 1998 Hodosh application.

All of the Claims of the Fischer I Patent Correspond to the Proposed Count

The limitations of claim 21 of the Fischer I patent are identical to the limitations of the proposed count.

Independent claim 1 of the Fischer I patent from which claim 21 depends recites a sticky dental composition adapted for use with a dental tray for treating sensitive teeth including a desensitizing agent for reducing dental pain sensations; and a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof, the dental composition having a stickiness so that the dental composition is capable of adhering and retaining a dental tray over a person's teeth for at least about one hour, wherein the dental tray is designed not to exert a mechanical pressure onto the person's teeth and gums. Thus claim 1 of the Fischer I patent is identical to the proposed count except that said claim 1 does not recite the bleaching agent. Dependent claim 21 of the Fischer I patent further recites that the dental composition includes a bleaching agent.

Thus the limitations of claim 21 of the Fischer I patent are identical to the limitations of the proposed count and therefore, to the extent that claim 21 of the Fischer I patent is patentable, so is the proposed count.

As discussed above independent claim 1 is identical to the proposed count except that claim 1 of the Fischer I patent does not recite a bleaching agent. The omission of the active agent, i.e. the bleaching agent, would be obvious to one skilled in the art when only a desensitizing effect is desired. (Milton Hodosh Affidavit ¶ 3). Moreover, claim 1 of the Fischer I patent contemplates the inclusion of some other active dental agent (e.g. a bleaching agent). (See Fischer I patent specification, col. 9, ll. 1-46). Accordingly it is submitted that claim 1 of the

Fischer I patent fails to define a separately patentable invention over the proposed count and thus corresponds to the proposed count.

Claims 2-17 depend either directly or indirectly from claim 1 and merely recite routine limitations. Moreover, the specification does not subscribe any criticality to the limitations recited in claim 2-17. Accordingly claims 2-17 are not patentable in view of the count and also correspond to the proposed count.

Independent claim 18 essentially recites the same elements as those recited in claim 1 but also includes the additional limitation that the carboxypolymethylene is neutralized in order that the resulting dental composition has a pH in the range from about 4 to about 9. It would have been obvious to one skilled in the art at the time the invention was made to neutralize the composition to proved it with a pH in the desired range. (Milton Hodosh Affidavit ¶ 4). Further, the specification does not subscribe any criticality to this limitation. Accordingly claim 18 recites the same basic elements as those recited in claim 1 and the proposed count except for the bleaching agent.

Claim 22 is directly dependent upon claim 18 and recites that the dental composition further includes a dental bleaching agent. Thus the limitations of claim 22 are essentially identical to the limitations of the proposed count. Accordingly it is submitted that claim 22 corresponds to the proposed count.

Claim 20 is an independent claim that essentially recites the same elements as recited in claim 1 but also includes that additional limitations that the dental composition includes “polypol, a base, and optionally water”. It is submitted that these ingredients are well known in the field and the inclusion of said ingredients would have been obvious to one skilled in the art. Claim 20 also recites that the “dental composition ... is neutralized to a pH in a range from about 5 to about 7”. As noted above it would have been obvious to one skilled in the art to neutralize the dental

composition to provide a desired pH range. (Milton Hodosh Affidavit ¶ 5). Finally the specification does not subscribe any criticality to these limitations. Accordingly claim 20 essentially recites the same elements as those recited in claim 1 and the present count except for the bleaching agent.

Claim 23 is dependent upon claim 20 and further recites that the dental composition includes a bleaching agent. Thus the limitations of claim 23 are essentially identical to the limitations of the proposed count. Accordingly it is submitted that claim 23 corresponds to the proposed count.

In view of the above it is submitted that all of the claims of the Fischer I patent correspond to the proposed count.

All of the Claims of the Fischer II Patent Correspond to the Proposed Count

Independent claim 1 of the Fischer II patent recites a method for treating sensitive teeth including the steps of:

- (a) providing a dental tray configured to cover a person's teeth and hold a quantity of a dental composition therein, the dental tray further being configured so that it is designed not to exert mechanical pressure onto the person's teeth and gums;
- (b) placing a quantity of tooth desensitizing dental composition within the dental tray, the dental composition including a desensitizing agent for reducing dental pain sensations and a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof;
- (c) positioning the dental tray over the person's teeth for a prescribed treatment period, the dental composition adhering and retaining the dental tray over the person's teeth during the prescribed treatment period; and
- (d) removing the dental tray from the person's teeth.

Steps (a), (c) and (d) recite well known steps for using a dental tray. Specifically, with regard to step (a), dental trays configured to cover a person's teeth a hold a quantity of dental composition which is configured not to exert a mechanical pressure onto the person's teeth and gums are well known in the art. With regard to step (c), positioning the dental tray over a person's teeth for a prescribed treatment period is well known. Finally removing the dental tray is also a well known step.

An article by Milton Hodosh, the sole inventor named in the present application, published on November 11, 1982, entitled "Potassium Nitrate Gel-Sleeve: An Effective Procedure for Dentinal Hypersensitivity" discloses a method for treating hypersensitive teeth. In the method the use of a dental "sleeve", i.e. a thin dental tray formed from a thin piece of plastic, and the steps described in claim 1 of the Fischer II patent relating to the use of such a dental tray are set forth. In the method described in the article a desensitizing cream or gel containing 5% potassium nitrate is placed in the tray and the tray is placed over a patient's teeth for 15-30 minutes per treatment. A copy of the article is attached hereto as Exhibit 5.

In view of the foregoing it is submitted that the "invention" of claim 1 of the Fischer II patent is the composition recited in step (b). Specifically, the dental composition including a desensitizing agent for reducing dental pain sensations and a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof. This composition is essentially identical to the composition of the proposed count except for the presence of a bleaching agent.

Claim 21 of the Fischer II patent further recites that the composition recited in claim 1 further includes a bleaching agent. Thus the limitations of claim 21 are essentially identical to the limitations of the proposed count. Accordingly claim 21 corresponds to the proposed count.

As discussed above with regard to claim 1 of the Fischer I patent, the omission of the active agent, i.e. the bleaching agent, from the composition in claim 1 of the Fischer II patent

would be have been obvious to one skilled in the art where only a desensitizing effect was desired. (Milton Hodosh Affidavit ¶ 6). Further claim 1 of the Fischer II patent contemplates the inclusion of some other active dental agent. (See Fischer '870 specification, col. 9, ll. 1-47) Accordingly claim 1 of the Fischer II fails to define a separately patentable invention over the proposed count and corresponds to the present count.

Claims 2-11 and 21 of the Fischer II patent and merely recite routine limitations. Further these limitations are not designated in the specification as being critical to the invention. Accordingly it is submitted that claims 2-11 of the '870 patent also correspond to the present count.

Claim 12 is an independent claim which is essentially identical to claim 1 but further recites that the dental composition has a stickiness "in order that the dental tray composition is capable of retaining and holding a dental tray that is designed not to exert mechanical pressure onto a person's teeth and gums over a person's teeth for at least about one hour". This "limitation" to the method merely describes a property of the underlying inventive composition and does not add any additional "step" to the claimed method. Accordingly claim 12 is essentially directed to the same composition as that recited in the proposed count except for the presence of a bleaching agent.

Claim 22 directly depends from claim 12 and recites that the dental composition further includes a bleaching agent. Thus the limitations of claim 22 are essentially identical to the limitations of the proposed count. Accordingly claim 22 corresponds to the proposed count.

As discussed above with respect to claim 1 of the Fischer I patent and claim 1 of the Fischer II patent the composition recited in claim 12 it would have been obvious to one skilled in the art in view of the proposed count to omit the bleaching agent where only a desensitizing effect was desired. (Milton Hodosh Affidavit ¶ 7). Therefore claim 12 fails to define a separately patentable invention over the present count and corresponds to the proposed count.

Claims 13-16 and 22 of the Fischer II patent and merely recite routine limitations. Further these limitations which are not designated in the specification as being critical to the invention. Accordingly claims 13-16 of the Fisher II patent also correspond to the present count.

Independent claim 17 of the Fischer II patent recites a method for simultaneously treating sensitive teeth and diseased gums including essentially the identical steps recited in claim 1 of the Fischer '870 patent. The only additional limitation is that the tackifying agent comprising carboxypolymethylene is neutralized to a pH in a range from about 4 to 9. As discussed above it would have been obvious to one skilled in the art to neutralize the tackifying agent to provide a desired pH range. (Milton Hodosh Affidavit ¶ 8) Accordingly claim 17 again essentially recites the same composition of the proposed count except for the bleaching agent.

Claim 23 depends directly from claim 17 and further recites that the claimed composition includes a bleaching agent. Thus the limitations of claim 23 are essentially identical to the limitations of the proposed count. Thus claim 23 corresponds to the proposed count.

Claims 18-20 and 23-24 and merely recite routine limitations. These limitations are not designated in the specification as being critical to the invention. Accordingly claims 18-20 of the '870 Fischer patent also correspond to the present count.

In view of the above it is submitted that all of the claims of the '870 Fischer patent correspond to the proposed count.

All of the Claims of the Fischer III Patent Correspond to the Proposed Count

Independent claim 1 of the Fischer III patent reads as follows:

1. A sticky dental composition for treating a person's teeth, gums, or a combination thereof and adapted for use with a dental tray designed so as not to exert mechanical pressure on

a person's teeth and gums, said composition comprising:

at least one dental agent selected from the group consisting of dental bleaching agents, anticariogenic agents, antimicrobial agents, and mixtures of the foregoing for providing a desired treatment of a person's teeth, gums or a combination thereof; and

a tackifying agent comprised of carboxypolymethylene, which includes any reaction products of carboxypolymethylene, the dental composition having a stickiness so that the dental composition is capable of adhering and retaining, for a length of time in order to carry out the desired treatment, a dental tray that is designed so as to not exert a mechanical pressure onto the person's teeth and gums.

Thus claim 1 of the Fischer III patent essentially recites the same elements as those recited in the proposed count except for a desensitizing agent. Claim 1 of the Fischer III patent fails to define a separately patentable invention over the proposed count since it defines a bleaching composition that does not necessarily include a desensitizing agent which would be obvious in view of an identical bleaching composition that includes a desensitizing agent (i.e. the proposed count). Alternatively the composition of claim 1 is an intermediate composition that would be produced *en route* to producing the composition recited in the proposed count. That is, if one was producing a bleaching composition having desensitizing properties as recited in the proposed count one would combine a dental bleaching agent with the tackifying agent during the formulation of the composition according to the proposed count. Accordingly claim 1 of the Fischer III patent fails to define a separately patentable invention over the proposed count and corresponds to the proposed count.

Claims 2-15 depend either directly or indirectly from claim 1 and merely recite routine limitations. Claims 2-15 do not add any limitations which are designated in the specification as being critical to the invention. Accordingly claims 2-15 of the Fischer III patent also correspond to the proposed count.

Independent claim 16 of the Fischer III patent is essentially identical to claim 1 but further recites that the carboxypolymethylene of the dental composition is “treated with a base so that the resulting dental composition has a pH in a range from about 5 to about 7”. As discussed above it would have been obvious to one skilled in the art to neutralize the composition to provide a desired pH range. (Milton Hodosh Affidavit ¶ 9). Accordingly claim 16 also corresponds to the proposed count for the reasons set forth above with respect to claim 1 of the Fischer III patent.

Claim 17 is dependent upon claim 16 and merely further defines the basic invention recited therein. Claim 17 does not add any limitation which is designated in the specification as being critical to the invention. Accordingly claim 17 of the Fischer III patent also corresponds to the proposed count.

Independent claim 18 of the Fischer III patent is essentially identical to claim 1 but further recites that the sticky matrix material includes a “polyol, a base and optionally water”. It is submitted that these additional ingredients would have been obvious to one skilled in the art at the time the invention was made. In addition independent claim 18 recites that the base is “included in an amount so that the resulting dental composition has a pH in a range from about 5 to about 7”. As discussed above it would be obvious to one skilled in the art to neutralize the composition to produce a desired pH range. (Milton Hodosh Affidavit ¶ 10) In view of the foregoing claim 18 corresponds to the proposed count for the same reasons set forth above with respect to claim 1 of the Fischer III patent.

Independent claim 19 recites a “system” for treating a person’s teeth or gums including “a dental tray designed to exert mechanical pressure on the person’s teeth and gums” and a dental composition which is essentially identical to the composition recited in claim 1. It is submitted that “a dental tray designed not to exert mechanical pressure on the person’s teeth and gums” is well known in the art. Accordingly the “invention” of claim 19 is the dental composition. As discussed above with respect to claim 1 of the Fischer III patent the claimed composition corresponds to the present count. Accordingly claim 19 of the Fischer III patent corresponds to

the present count.

Claims 20-22 of the Fischer III patent merely recite routine limitations. Further these limitations are not designated in the specification as being critical to the invention. Accordingly claims 20-22 of the Fischer III patent also correspond to the present count.

In view of the above it is submitted that all of the claims of the Fischer '249 patent correspond to the present count.

All of the Claims of The Fischer IV Patent Correspond to the Proposed Count

Claim 1 of the Fischer IV patent reads as follows:

1. A method of providing a desired treatment of a person's teeth, gums, or a combination thereof, the method comprising:

providing a dental tray that is designed so as to not exert to [sic] mechanical pressure onto the person's teeth and gums;

introducing a quantity of a dental composition into the dental tray, the dental composition having a stickiness in order to retain and adhere the dental tray over the person's teeth for a time in order to carry out the desired treatment, the dental composition including:

at least one agent selected from the group consisting of dental bleaching agents, anticariogenic agents, antimicrobial agents, and mixtures thereof for providing the desired treatment of the person's teeth, gums, or a combination thereof; and

a tackifying agent comprised of carboxypolymethylene, including any reaction products thereof, and that imparts at least a portion of said stickiness to the dental composition;

placing the dental tray containing the dental composition over the person's teeth in a manner so that the dental composition retains and adheres the dental tray over the person's teeth;

leaving the dental tray over the person's teeth so as to carry out the desired treatment; and
removing the dental tray from the person's teeth.

The various steps as recited in claim 1 are well known steps for using a dental tray. The

steps are set forth in the Hodosh article attached hereto as Exhibit 5. Accordingly the “invention” of claim 1 of the Fischer IV patent is the composition recited in the claim. Specifically, the dental composition including at least one dental agent selected from the group including a desensitizing agent for reducing dental pain sensations and a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof.

Thus claim 1 of the Fischer IV patent essentially recites the same elements as those recited in the proposed count except for a desensitizing agent. Claim 1 of the Fischer IV patent fails to define a separately patentable invention over the proposed count since it defines a bleaching composition that does not necessarily include a desensitizing agent which would be obvious in view of an identical bleaching composition that includes a desensitizing agent (i.e. the proposed count). Alternatively claim 1 of Fischer IV patent defines an intermediate composition that would be produced *en route* to producing the composition recited in the proposed count. That is, if one was producing a bleaching composition having desensitizing properties as recited in the proposed count one would combine a dental bleaching agent with the tackifying agent during the formulation of the composition according to the proposed count. Thus claim 1 of the Fischer IV patent fails to define a separately patentable invention over the proposed count and corresponds to the proposed count.

Claims 2-14 and 19-20 of the Fischer IV patent depend either directly or indirectly from claim 1 and merely recite routine limitations. Further these limitations which are not designated in the specification as being critical to the invention. Accordingly claims 2-14 of the Fischer IV patent also correspond to the proposed count.

Independent claim 15 of the Fischer IV patent recites a method which is essentially identical to the method recited in claim 1 however the method recited in claim 15 specifies that the “dental composition has a pH in a range from about 5 to about 7”. As discussed above it would be obvious to one skilled in the art to treat the composition to obtain a desired pH range. (Milton Hodosh Affidavit ¶ 11). According claim 15 also corresponds to the proposed count for

the reasons set forth above with respect to claim 1 of the Fischer IV patent.

Claim 16 depends from claim 15 and merely defines parameters for the dental tray used in the method of claim 15. It is submitted that these parameters are either well known in the field and/or would be an obvious design choice to one skilled in the art. Accordingly it is submitted that claim 16 also corresponds to the proposed count.

Independent claim 17 of the Fischer IV patent recites a method which is essentially identical to the method recited in claim 1 however the method recited in claim 17 specifies that the dental agent is a antimicrobial agent and that the dental composition has a pH in a range from about 5 to about 7. It would be obvious to one skilled in the art to treat the composition to obtain a desired pH range. (Milton Hodosh Affidavit ¶ 12) In addition antimicrobial agents are known active ingredients in the dental composition field. (Milton Hodosh Affidavit ¶ 13). Thus claim 17 does not define a separately patentable invention over the present count and corresponds to the proposed count.

Claim 18 depends from claim 17 and merely defines parameters for the dental tray used in the method of claim 17. It is submitted that these parameters are either well known in the field and/or would be an obvious design choice to one skilled in the art. Accordingly it is submitted that claim 17 also corresponds to the proposed count.

Thus all of the claims of the Fischer IV patent correspond to the proposed count.

Showing Under 37 C.F.R. 1.608(b)

37 C.F.R. 1.608(b) provides that where the effective filing date of an application is more than three months after the filing date of a patent, the applicant, before an interference will be declared, shall file evidence which demonstrate that the applicant is *prima facie* entitled to a judgement relative to the patentee and an explanation stating with particularity the basis upon

which the applicant is *prima facie* entitled to the judgment. In the present case the earliest claimed filing dates of the Fischer I-IV patents discussed above is May 30, 1997. As discussed in more detail below Milton Hodosh reduced to practice the invention of the proposed count prior to May 30, 1997 and thus is *prima facie* entitled to judgement relative to Fischer.

On a date prior to May 30, 1997 Milton Hodosh, the sole inventor named in the 09/072,504, conceived of tooth bleaching and desensitizing composition. (Milton Hodosh Affidavit ¶ 14). On a date prior to May 30, 1997 Milton Hodosh formulated a bleaching composition by combining a bleaching agent and KNO_3 . (Milton Hodosh Affidavit ¶ 15). The bleaching agent was a commercial available bleaching agent know as "Karisma". (Milton Hodosh Affidavit ¶ 16).

On information and belief "Karisma" contains carbamide peroxide as the active bleaching agent and a stick matrix material which includes carboxypolymethylene. (Milton Hodosh Affidavit ¶ 17). Thus the resultant dental composition employed in the test included (a) a desensitizing agent for reducing dental pain sensations; (b) a tackifying agent selected from the group consisting of carboxypolymethylene, gums, proteins, and mixtures thereof, the dental composition having a stickiness so that the dental composition is capable of adhering and retaining a dental tray over a person's teeth for at least about one hour, wherein the dental tray is designed not to exert a mechanical pressure onto the person's teeth and gums; and a bleaching compound. These elements are identical to the elements recited in the proposed count.

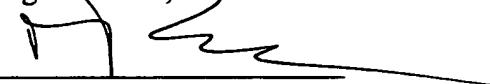
On a date prior to May 30, 1997 Milton Hodosh conducted a test to determine whether the dental composition corresponding to the proposed count function functioned to achieve its intended purpose. (Milton Hodosh Affidavit ¶ 18). The factual details and results of this test are set forth in the affidavit of Milton Hodosh under 37 C.F.R. 1.608(b) filed concurrently herewith and in the research notes of Milton Hodosh attached to said affidavit. Further the factual details and results of the test have been corroborated by Dr. Alex Hodosh in an affidavit which has also been filed concurrently herewith.

The dental composition was administered to at least nine patients using a dental tray which was adapted to hold the dental composition adjacent the patient's teeth. (Milton Hodosh Affidavit ¶ 19) In each of patients the dental bleaching composition effectively whitened the patient's teeth and no hypersensitivity was reported. (Milton Hodosh Affidavit ¶ 20). The test proved that the dental composition functioned to achieve its intended purpose.

The above facts establish that dental composition according to the proposed count was reduced to practice by Milton Hodosh prior to earliest filing date of any of the Fischer patents discussed above, i.e. before May 30, 1997. Thus, the applicant has demonstrated that he is *prima facie* entitled to judgment relative to the patentee and an interference should thus be declared.

Respectfully submitted,
Steinberg & Raskin, P.C.

By: _____


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